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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,847	08/09/2006	Philipp Kropf	03728/0205090-US0	7019
7278	7590	11/06/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER YARNALL, MEGAN LEIGH	
			ART UNIT 4138	PAPER NUMBER
			MAIL DATE 11/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/597,847

Applicant(s)

KROPF ET AL.

Examiner

Megan Yarnall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 080906.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 36 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakin 2003/0163202.

3. Re claim 18, Lakin teaches prosthesis 10 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 12 having outer surface 16 that is configured to lie in an articular fossa and attachment to a surface, shell section 12 having cavity 18 for receiving a bone end (par.32); and crown 20 that partitions cavity 18 of shell section 12 into a first cavity and a second cavity (fig.1); wherein a shape of the shell section is at least a section of a hemisphere (par.32, II.3-5) and a free edge of crown 20 lies in the same plane as a free edge of shell section 12 (fig.9).

4. Re claim 36, Lakin teaches prosthesis 10 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 12 having outer surface 16 that is configured to lie in an articular fossa and attachment to a surface, shell section 12 having cavity 18 for receiving a bone end (par.32); and crown 20 that partitions cavity 18 of shell section 12 into a first cavity and a second cavity (fig.1); wherein a shape of the shell section is at least a section of a hemisphere (par.32, II.3-5)

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and a free edge of crown 20 is displaced from a plane in which a free edge of shell section 12 lies (fig.1).

5. Re claim 39, Lakin further teaches prosthesis 10 wherein the free edge of crown 20 does not intersection the plane in which the free edge of shell section 12 lies (fig.1).

6. Claims 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutter et al. 4,332,036.

7. Re claim 36, Sutter teaches prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14); and crown 7 that partitions the cavity of the shell section into a first cavity and a second cavity (fig.1); wherein a shape of shell section 3 is at least a section of a hemisphere (col.3, ll.17-19) and a free edge of the crown is displaced (s) from a plane in which a free edge of shell section 3 lies (fig.3).

8. Re claim 37, Sutter further teaches prosthesis 1 wherein the free edge of crown 7 projects by up to 5 mm over the plane in which the free edge of shell section 3 lies. Sutter discloses the diameter of the crown, d, to be equal to 10-25 mm (col.4, ll.8-10), d preferably equal to at least 30% of the length L (col.4, ll.18-20), and projection distance, s, preferably equal to at most 40% of L (col.4, ll.23-25). From these values s may range from 0.9-2.25 mm, and is therefore less than 5 mm.

9. Re claim 38, Sutter further teaches prosthesis 1 wherein the free edge of crown 7 projects from about 1-3 mm (col.4, ll.8-25).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 19-21, 35, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakin 2003/0163202.

12. Re claims 19-21, Lakin teaches the invention as claimed and as discussed above. Lakin further discloses a spherical shell section wherein shell component 12 can be a partial hemisphere (par.32, ll.4-6). This means the shell height may be less than 100% of the radius of the ball. While Lakin does not specifically disclose a shell height that is about 65-90%, 70-85%, or 80% of the radius of the ball, it would be obvious to one of ordinary skill in the art at the time of the invention to pursue the finite number of known options within his or her technical grasp. Further, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

13. Re claim 35, Lakin teaches the invention as claimed and as discussed above. Lakin further teaches a screw locking mechanism for coupling the two components (par.34, ll.1-4). While the location of the threads is not positively disclosed as being on an outer surface of the crown and/or the inner surface of the shell section, it would have been a matter of design choice to place the threads in either location, which a person of

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ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B). Further, it has been held that making parts separable for any desirable reason is an obvious extension of prior art teachings (In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) MPEP V C).

Therefore, it would have been obvious at the time of the invention to modify Sutter in view of Lakin in order to hold the components together without any appreciable movement as taught by Lakin, par.34, ll.4-6.

14. Re claim 40, Lakin teaches the invention as claimed and as discussed above. In figure 1, Lakin discloses prosthesis 10 wherein a free edge of crown 20 is a distance away from the plane containing the free edge of shell section 12. While Lakin does not specifically disclose a distance of up to 5 mm from the plane containing the free edge of the shell section, it has been held that limitations relating to size are not sufficient to patentably distinguish over the prior art (In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A).

15. Re claim 42, Lakin teaches the invention as claimed and as discussed above. Lakin further teaches a plurality of shells and stems of various diameters in order to allow a surgeon to pick from a variety of components to match the patient's anatomy (par.38). While Lakin does not positively disclose a set wherein the ratio of the height of the shell section to a respective ball diameter is equal for the different prosthesis and a diameter of each crown amounts to the same percentage of a diameter of the spherical shell section, it has been held that changes in shape are a matter of design choice,

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which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

16. Claims 18, 22-31, 33, 34, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. 4,332,036.

17. Re claim 18, Sutter teaches prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint comprising: spherical shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14); and crown 7 that partitions the cavity of the shell section into a first cavity and a second cavity (fig.1); wherein a shape of shell section 3 is at least a section of a hemisphere (col.3, ll.17-19) and a free edge of crown 7 lies outside the plane of the free edge of shell section 3 (fig.1). While Sutter discloses the free edge of crown 7 extending beyond the plane of the free edge of shell section 3, and does not disclose a prosthesis wherein a free edge of the crown lies in the same plane as a free edge of the shell section, it has been held that limitations relating to size are not sufficient to patentably distinguish over the prior art (In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A).

18. Re claim 22, Sutter further teaches prosthesis 1 wherein first cavity 7 has a circular shape and second cavity 3c has an annular shape (fig.1).

19. Re claim 23, Sutter further teaches prosthesis 1 wherein innermost end of the crown 7b is integrally connected to the inner surface of the shell section so as to form a single integral structure (col.3, ll.25-27).

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20. Re claim 24, Sutter further teaches prosthesis 1 wherein at least one of the inner surface of the shell section and a surface of the crown is configured for contact with the bone end and is therefore a roughened surface (col.5, ll.46-50).

21. Re claim 25, Sutter further teaches prosthesis 1 wherein the crown has at least one opening 7e formed therein to provide communication between the first and second cavities (fig.1).

22. Re claim 26, Sutter further teaches prosthesis 1 wherein the at least one opening comprises at least five openings (figs.1, 20).

23. Re claim 27, Sutter further teaches prosthesis 1 wherein at least one of an inner surface and an outer surface of the crown has a relief structure formed as a part thereof (col.7, ll.26-31).

24. Re claim 28, Sutter further teaches prosthesis 1 wherein the relief structure comprises a fluting that is formed by ring beads that extend circumferentially around the crown (col.7, ll.26-31; fig.11).

25. Re claim 29, Sutter further teaches prosthesis 1 wherein the inner surface of the shell section includes a relief structure that extends along an edge of the shell section (col.3, ll.53-60; col.6, ll.1-17; figs. 7, 11).

26. Re claim 30, Sutter further teaches prosthesis 1 wherein the relief structure comprises fluting formed circumferentially around the inner surface of the shell section (figs. 2, 7, 11).

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27. Re claim 31, Sutter further teaches prosthesis 1 wherein the crown and shell section are separate parts and are constructed to be securely coupled to one another (col.3, ll.25-27).

28. Re claim 33, Sutter further teaches prosthesis 1 wherein the crown has a circular shape (col.3, l.22).

29. Re claim 34, Sutter further teaches prosthesis 1 wherein the crown is arrayed in a coaxial manner (col.3, ll.22-23; fig.1).

30. Re claim 41, Sutter further teaches a procedure for implantation of a prosthesis in a bone comprising the steps of: preparing the bone and forming a groove in the bone (col.5, ll.4-14; figs. 4, 5); prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint, prosthesis 1 including spherical shell section 3 and crown 7, shell section 3 having outer surface 3a that is configured to lie in an articular fossa and attachment to a surface, shell section 3 having cavity 3c for receiving a bone end (fig.14); crown 7 partitioning the cavity of the shell section into a first cavity and a second cavity (fig.1), wherein a shape of shell section 3 is at least a section of a hemisphere (col.3, ll.17-19) and a free edge of crown 7 lies outside the plane of the free edge of shell section 3 (fig.1); and inserting the prosthesis onto the bone such that the crown is received in the groove formed in the bone (col.5, ll.14-17; fig.6). While Sutter discloses the free edge of crown 7 extending beyond the plane of the free edge of shell section 3, and does not disclose a prosthesis wherein a free edge of the crown lies in the same plane as a free edge of the shell section, it has been held that limitations

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relating to size are not sufficient to patentably distinguish over the prior art (In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) MPEP 2144.04 IV A).

31. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. 4,332,036 in view of Lakin 2003/0163202. Sutter teaches the invention as claimed and as discussed above. Sutter does not teach a prosthesis wherein the crown and shell section are constructed to be threadingly coupled to one another by means of threads formed on at least one of an outer surface of the crown and the inner surface of the shell section.

Lakin teaches a screw locking mechanism for coupling the two components (par.34, ll.1-4). While the location of the threads is not positively disclosed as being on an outer surface of the crown and/or the inner surface of the shell section, it would have been a matter of design choice to place the threads in either location, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B). Further, it has been held that making parts separable for any desirable reason is an obvious extension of prior art teachings (In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) MPEP V C)..

Therefore, it would have been obvious at the time of the invention to modify Sutter in view of Lakin in order to hold the components together without any appreciable movement as taught by Lakin, par.34, ll.4-6.

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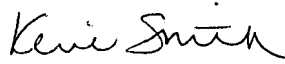
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Yarnall whose telephone number is 571-270-3071. The examiner can normally be reached on Monday-Thursday 6:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 571-272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


my
October 31, 2007


KIMBERLY S. SMITH
PRIMARY EXAMINER

11/1/07